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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,994	11/12/1999	JAMES J. FORT,	6487.US.01	1116

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
VENKAT, JYOTHSNA A	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/438,994	FORT, ET AL.	
	Examiner	Art Unit	
	JYOTHSNA A. VENKAT Ph. D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-10,13-15 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-10,13-15 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of remarks and statement of common ownership over U. S. Patent 6,465,011, both filed on 1/16/07. Claims 1, 8-10, 13-15 and 22 are pending in the application and the status of the application is as follows:

Claim Rejections - 35 USC § 103

Claims 1, 8-10, 13-15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Article by Palmier et al. in S.T. P. Pharma Sciences, pp 188-194 (1996) (Palmier et al.) and U. S. Patent 5,545,628 ('628).

The instant application is claiming a pharmaceutical composition comprising:

1. A solid dispersion of fenofibrate or a salt or ester there of

2. Hydroxypropylmethylcellulose (HPMC)

3. Polyethylene glycol (PEG) carrier

a method of preparing the composition and method of treating hyperlipidemia comprising administering the composition.

Palmier et al. teaches dissolution studies of Fenofibrate solid dispersions using Fenofibrate and PEG 4000 in solvent ethanol. See page 188, where the article teaches that Fenofibrate is water insoluble molecule and is very soluble in ethanol and the article teaches PEG 4000 as a carrier because of its ethanol solubility and physiologically compatibility. Claims13 and 18 use ethanol as solvent. The difference between the article and the application is article does not teach ingredient 2 for the preparation of solid dispersions. However patent '628 teaches pharmaceutical compositions containing fenofibrate. See col.1, lines 5-10, see col.2, lines 39-55 and see specially lines 50-51 where the patent teaches that HPMC is a suspension

stabilizer which avoids the formation of fenofibrate crystals. This is same as claimed HPMC as the crystallization inhibitor. See col.3, lines 1-35 for surfactants. See col.4, lines 1-30 for the preparation and packing into the hard gelatin capsules, see col.7 lines 10-15 where the patent teaches HPMC with fenofibrate. See also pharmokinetical study. Patent does not teach tablet. Dosage forms in the form of tablets, capsules are conventionally used and preparing the compositions in the form of tablet is obvious to one of ordinary skill in the art.

Accordingly it would have been obvious to one of ordinary skill in the art to prepare fenofibrate composition taught by Palmier etal, article using ethanol as solvent and PEG as the carrier and adding HPMC so that solid dispersions are formed. One of ordinary skill in the art would be motivated to add HPMC in fenofibrate dispersions of Palmier et al. with the reasonable expectation of success that HPMC avoids the formation of Fenofibrate crystals. This is a prima facie case of obviousness.

Response to Arguments

Applicant's arguments filed 1/16/07 have been fully considered but they are not persuasive.

Applicants' argue:

> "The teachings of Palmieri et al. are directed to the preparation of a solid dispersion of fenofibrate in PEG 4000 using evaporation or fusion methods, in which reference it is explained that fenofibrate solubility is substantially increased by the solid dispersion formation. Palmieri et al. does not teach, suggests, or discuss the use of HPMC to improve the solubility of said fenofibrate solid dispersion.

The teachings of '628 are directed to a homogeneous fenofibrate solution of fenofibrate (Col. 2, lines 56-60). The final composition is maintained in liquid state and capsules are filled with this liquid composition using a liquid filling capsule machine (Col. 4, lines 1-13). Fenofibrate is never re-solidified, therefore '625 does not teach or describes fenofibrate in solid state, as the claims of the present application do".

In response to the above argument, claim 1 of instant application, recites:

Currently Amended) A pharmaceutical composition comprising a solid dispersion of fenofibrate, or a salt or ester thereof, and hydroxypropylmethylcellulose (HPMC) crystallization inhibitor in a polyethylene glycol (PEG) carrier.

Palmieri et al. article teaches Fenofibrate dispersions except the claimed HPMC and patent '628 teaches Fenofibrate compositions and at col.2 teaches to one skilled in the art that certain compounds are added to prevent crystal formation. See below for relevant portions of col.2 of patent '628.

> The present invention also relates to the addition of a suspension stabilizer to the molten solution of fenofibrate-polyglycolyzed glycerides. The suspension stabilizer avoids the formation of fenofibrate crystals during the cooling of the filled hard gelatin capsules. Suitable suspension stabilizers which may be used are, for example, cellulose derivatives, such as hydroxypropylcellulose, hydroxypropylmethyl cellulose, methyl cellulose, and hydroxyethylcellulose, povidone, poloxamers, α, Ω-hydroxy-poly(oxyethylene) poly(oxypropylene)-poly(oxyethylene)bloc polymers. Other suspension stabilizers equivalent to these stabiliers may, of course, also be used.

Therfore one of ordinary skill in the art would be motivated to use crystallization inhibitor HPMC so that crystals of fenofibrate are not formed during preparations of solid dispersions of Fenofibrate. With respect to method of preparation claimed in claim 15, steps c-e are optional and therefore the method of use claims are also obvious. The claims are prima facie obvious over the combination of Palmieri et al. and patent '628 since one of ordinary skill in the art would be motivated to prepare fenofibrate composition taught by Palmieri et al. using ethanol as solvent and PEG as the carrier so that solid dispersions are formed and add HPMC in fenofibrate dispersions of Palmieri et al. with the reasonable expectation of success that HPMC avoids the formation of Fenofibrate crystals taught by patent '628, in analogous Fenofibrate compositions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,8-10 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3and 5-9 of U.S. Patent No. 6,465,011 ('011) in view of Palmier article.

Instant application and claims to the patent are claiming compostions, dosage forms in the form of capsule or tablet and method of treating hyperlipidemia using fenofibrate and amorphous polymer, which is HPMC. Instant application is also claiming PEG as the carrier, which is not claimed in the patent. Palmier article teaches Fenofibrate dispersions using PEG 4000 as the carrier. It would be obvious to prepare compostions of '011 claimed in the patent and add PEG with the reasonable expectation of success that increased dissolution and increased bioavailability of Fenofibrate dispersions is obtained.

This rejection is maintained. Applicants did not address this rejection. Submitting common ownership statement would not obviate obviousness–type double patenting rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J. Venkat

JYOTHSNA A VENKAT Ph. D
Primary Examiner
Art Unit 1615

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